AF IFW

PATENT

I hereby certify that this correspondence and its enclosures are being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450 on June 13, 2005.

David E. Jefferies, Esq., Reg. No. 46,800 — 6/13/05 Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.:	09/978,457
Filed:	October 16, 2001
Group Art Unit:	3763
Examiner:	Kathryn L. Thompson
Applicant:	Joseph J. Chang
Title:	**Safety Intravenous Catheter**
Attorney Ref.:	56301P579D (MDXVA-33DV-114)
Confirmation No.:	5126

Cincinnati, Ohio 45202 June 13, 2005

Commissioner for Patents
U.S. Patent and Trademark Office
Post Office Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL

Submitted herewith:

Transmittal;
Appeal Brief (in triplicate);
Check in the amount of $500.00; and
Acknowledgement postcard.

The Office is authorized to charge Deposit Account 23-3000 if there is any additional charge or credit due.

David E. Jefferies
Reg. No. 46,800

WOOD, HERRON & EVANS, L.L.P.
2700 Carew Tower
441 Vine Street
Cincinnati, Ohio 45202-2917
(513) 241-2324
(513) 241-6234 (fax)

PATENT

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450 on June 13, 2005.

6/13/05

David E. Jefferies, Esq., Reg. No. 46,800 Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte

Appeal No. _____

Serial Number:	09/978,457
Filed:	October 16, 2001
Group Art Unit:	3763
Examiner:	Kathryn L. Thompson
Applicant:	Joseph J. Chang
Title:	**Safety Intravenous Catheter**
Attorney Ref.:	56301P579D (MDXVA-33DV-114)
Confirmation No.:	5126

Cincinnati, Ohio 45202 June 13, 2005

APPEAL BRIEF

This brief is in furtherance of Applicant's Notice of Appeal filed April 11, 2005, appealing the decision of Examiner issued in an Office Action dated January 12, 2005. During prosecution of this case, claims 1-7 and 9 have been twice rejected, and claims 8, 10, and 11 have been improperly withdrawn. A copy of the current claims appears in the Appendix to this brief. This brief is transmitted in triplicate.

06/17/2005 WASFAW1 00000020 09978457

01 FC:1402 500.00 OP

Real Party In Interest

The real party in interest in this appeal is Medex, Inc., a Corporation of Ohio having a place of business at 2231 Rutherford Road, Carlsbad, California 92008.

Related Appeals and Interferences

There are no such appeals or interferences known to appellant, the appellant's legal representative, or assignee, which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

Status of Claims

Although this appeal is filed after a first rejection of claims following a Request for Continued Examination, the claims have been twice or more rejected. Claims 1-7 and 9 stand rejected under 35 U.S.C. § 102, asserted to be anticipated by U.S. Patent No. 5,491,766 (Chang). Claims 8, 10, and 11 stand withdrawn by Examiner.

Status of Amendments

There are no amendments pending.

Summary of Claimed Subject Matter

The present application relates to tip protectors for shielding a needle tip. Referring to Figure 1 of the present application, reproduced below, a tip protector 20 includes a superstructure to enclose a needle tip 40.

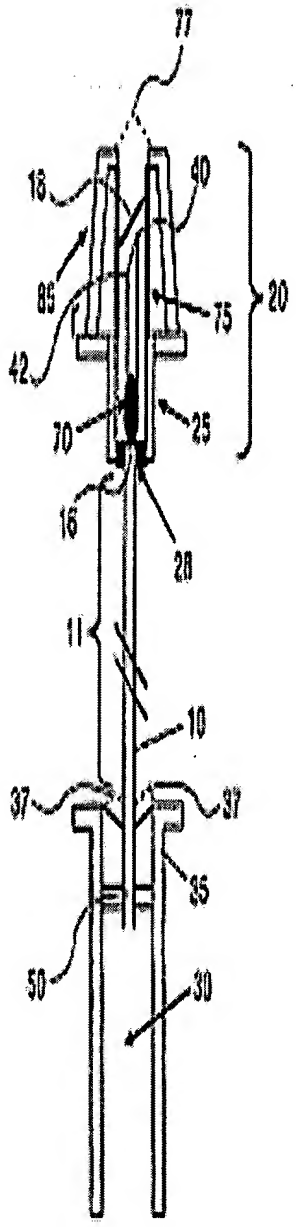


FIG. 1

This superstructure includes a proximal base 25 and a distal opening 77. A gasket 28 having an opening 16 is associated with the proximal base. A needle cannula shaft 11 can be slidably

received through opening 16 and distal opening 77 in an extended position (with the needle tip extending from the tip protector), or in a retracted position (to receive tip within superstructure, as shown in Fig. 1). Once retracted, structure is provided to block the tip protector distal opening 77 to enclose the needle tip. Independent claim 1 recites this structure as a "means coupled to the tip protector for blocking the tip protector opening." This means is described in the specification at page 7, lines 10-16, as a tab 18 resiliently mounted in the tip protector. When the needle cannula extends from tip protector, the tab bears against the needle shaft. As the tip protector is slid relative to the tip (such as by retracting needle), the tab pivots to block the distal opening and enclose the tip.

During retraction of the needle, structure is also provided to limit movement of the tip protector toward the needle tip. As recited in claim 1, this structure is a "means fixedly coupled to the needle cannula shaft at a predetermined location of the shaft for impeding movement of the tip protector along the needle cannula shaft beyond a predetermined distance from the needle cannula distal point." This means is described in the application at page 6, lines 6-18 as (1) a crimp 70 created at a specific location of the needle shaft, or (2) a protuberance applied over a specific location on the outer surface of the needle cannula shaft (such as by soldering or pressure fitting a durable O-ring therearound). As the needle is retracted, the crimp or protuberance will impact the gasket, and cannot pass therethrough, thereby limiting movement of tip protector. Previous tip protectors (such as that disclosed in Chang), include a superstructure having proximal and distal openings, a gasket, and a tab. However, the gasket was not used to limit movement of the needle and tip protector. Indeed, rather than any means fixedly coupled to the needle shaft as in the present invention, Chang used an external tether

coupled to the needle hub and tip protector to limit the distance the tip protector could slide along the needle.

Grounds of Rejection to be Reviewed on Appeal

(1) The rejection of claims 1-7 and 9 as anticipated under 35 U.S.C. § 102(b) over U.S. Patent No. 5,491,766 (Chang).

(2) The withdrawal of claims 8, 10, and 11 by Examiner.

Argument

I. Introduction

Examiner rejects claims 1-7, and 9 as anticipated by Chang. The rejection is improper because Chang does not disclose a means "fixedly coupled" to a needle shaft at a "predetermined distance" from the needle tip, as required by the claims. Examiner lamely points to an oval-shaped member (the proximal opening and/or gasket) that the needle of Chang passes through as though it was something fixedly coupled to the needle shaft. Appellant submits that it is impossible for a structure that the needle of Chang moves through to be fixedly coupled to the needle shaft. Appellant has repeatedly tried to explain this to Examiner, to no avail. This, however, is exemplary of the lack of attention exhibited by Examiner throughout prosecution of the present application. A further example of this is the Examiner's inexplicable withdrawal of claims 8, 10, and 11.

II. Examiner's Withdrawal of Claims 8, 10, and 11 is Improper

The present application was filed with claims 1 through 11 pending (claims 1-14 filed along with a Preliminary Amendment canceling claims 12-14). Examiner issued an Official Action (dated October 3, 2003) indicating that claims 1 through 14 were pending and making a

species election requirement between Figure 1 and Figure 2, without identifying which claims were believed to apply to which figure. However, the same restriction requirement was made (by a different Examiner) in the parent application (Serial No. 09/476,429 which has now issued as U.S. Patent No. 6,322,537). In that prior restriction requirement, it was set out that claims 1 through 11 correspond to Figure 1 and that claims 12 through 14 correspond to Figure 2. See Notice of Allowability mailed September 25, 2001 at page 2, entitled "Detailed Action" (listed in the Evidence Appendix and attached as Exh. A). In the parent application, the species corresponding to Figure 2, i.e., claims 12 through 14, was elected for prosecution and claims 1 through 11 cancelled. In the present case, the Office Action mailed October 3, 2003 made essentially the same restriction by classifying the two species as "(A) Figure 1; (B) Figure 2." Appellant elected the species of Figure 1, upon which claims 1-11 read, as those were the only claims then pending, notwithstanding Examiner's erroneous indication that claims 12-14 were also in the case.

As if to ignore the error in having even issued a restriction requirement, Examiner, in the Office Action dated January 20, 2004, suddenly took the position that claims 8, 10, and 11 no longer related to Figure 1 (i.e., species A). Examiner has never provided any logical basis to do so and Examiner is wrong. The subject matter of claims 8, 10, and 11 reads on both species (Figures 1 and 2) and so readily belong active in the present set of claims.

In this regard, the primary difference between Figures 1 and 2 is the presence or absence of the catheter in the drawing. Claims 12-14 which were elected in the parent include the catheter, whereas claims 1-11 do not recite the catheter and so are directed to the needle and its tip protector (whether it includes a catheter or not in view of the "comprising" language of the

claims). There is no basis, however, to assume that the features of claims 8, 10, or 11 are limited to the Figure 2 embodiment. The tab, superstructure and clip of those claims are shown as the same structure in both Figures. In this regard, Figure 1, shows a tab 18, superstructure 85 and metal clip 75, and so does Figure 2 with the same reference numbering. They thus clearly read on the species of either figure. Yet, Examiner inexplicably maintained her restriction and made it final. Perhaps this was simply done to try to avoid the embarrassment of admitting that a restriction had been made for which there was absolutely no basis.

Under the circumstances, it is respectfully submitted that claims 8, 10, and 11 should not have been withdrawn. Moreover, as will be argued below, claim 1 is submitted to be allowable over the cited Chang patent, thus entitling Appellant to reinstate claims 8, 10, and 11, which depend therefrom, in any event.

III. Claims 1-11 are Patentable Over Chang

The reasoning, or lack thereof, of the Examiner continued in her rejections of the claims over Chang. As an initial matter, Appellant acknowledges that, for purposes of this appeal, the tip protector of Chang may be considered to include a superstructure or housing with proximal and distal openings, a gasket, and a resilient tab as set forth in claim 1 of the present application. However, independent claim 1 of the present application further recites a "means fixedly coupled to the needle cannula shaft at a predetermined location of the shaft for impeding movement of the tip protector along the needle cannula shaft beyond a predetermined distance from the needle cannula distal point," i.e., a crimp or protuberance. Chang simply does not include such a means.

In fact, the difference between Chang and the present claims appeared so clear that Appellant believed the matter could be resolved by phone call, thereby obviating the need for further prosecution or appeal. However, the previously-described lack of attention to this case by Examiner was only exacerbated by her refusal to discuss the claims and potential amendments thereto via telephone, in spite of repeated attempts by Appellant's representative to do so, and in spite of the fact that many of these attempts were made following a non-final rejection, when the Appellant has the right to engage in such discussion. For example, following receipt of an Advisory Action dated August 11, 2004, Appellant's representative attempted to call Examiner on August 19, 2004 to try to reach an agreement on an amended Claim 1 that would resolve all outstanding issues. Appellant's representative left a voicemail message but has no record of receiving a return call prior to filing the Request for Continued Examination on September 9, 2004.

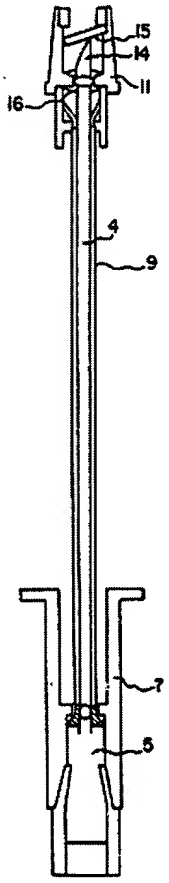
Also, following the currently-appealed Office Action dated January 12, 2005, Appellant's representative attempted to call Examiner on several occasions to try to reach an agreement on Claim 1 that would resolve all outstanding issues. Appellant's representative left voicemail messages on these occasions, but has no record of ever receiving a return call. Appellant's representative also attempted to call Examiner's Supervisory Primary Examiner, again leaving voicemail messages, but has no record of receiving a return call. By attempting to contact Examiner, Appellant had hoped to avoid the need for Appeal. However, due to the lack of response of Examiner, Appellant was unable to resolve outstanding issues and had to Appeal.

Regardless, it is clear that Chang does not include a "means fixedly coupled to the needle cannula shaft at a predetermined location of the shaft for impeding movement of the tip

protector along the needle cannula shaft beyond a pre-determined distance from the needle cannula distal point," as recited in claim 1 of the present application. When construed to cover the structure shown in the present application and equivalents thereof as required, there is nothing at all similar in Chang that is "fixedly coupled" to the needle at any "pre-determined distance" to "imped[e] movement" of the tip protector.

However, Examiner takes the position that there is "a crimp" shown in Chang, makes reference to "Figures 2c, 6a-6c" as if there is a crimp shown on the needle (Fig. 2C is reproduced below), and takes the position that the oval-shaped item in Chang (see reference numeral 16) is a crimp on the needle shaft. Figure 2C is reproduced below:

FIG. 2C



There is absolutely no basis in fact to consider the oval-shaped member to be a crimp on the needle. If it were such a crimp, it would move with the needle shaft. But the other drawings in the case make crystal clear that the oval-shaped member is affixed to the tip protector housing, and so does not move with the needle. Hence, it cannot be a crimp "fixedly coupled" to the needle.

For example, related Figures 2A and 2B show that exact same oval-shaped member in the same position with respect to tip protector 11, irrespective of the position (or even absence) of the needle shaft as reproduced below:

FIG. 2A

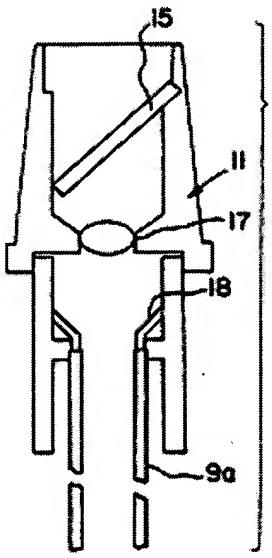
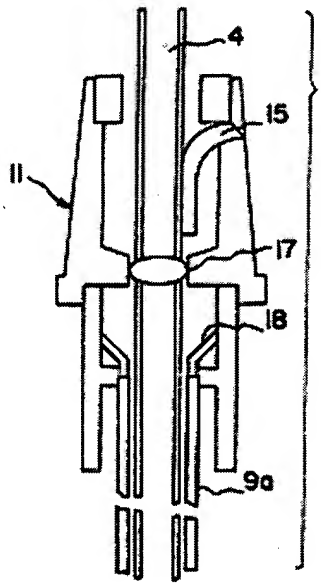


FIG. 2B



In fact, and referring to Figures 2A-2C, what Chang discloses is an external sleeve 9 or other elongatable material (i.e., a tether) that extends from the needle hub to the tip protector 11 so as to limit its axial travel towards the distal end 14 of the needle 4 (See column 7, lines 49-

51 of Chang). The tether is nothing like a crimp or protuberance on the needle shaft. And, indeed, with the tether, there is no reason to crimp the needle to impede movement of the tip protector. The tether does that!

Examiner does not dispute that Chang uses a tether. But without any foundation, or legal basis, Examiner creatively, but wrongly, identifies the oval-shaped member 16 of Chang as a structure to limit movement of tip protector "fixedly coupled" to the needle at a "predetermined distance" from the tip. This is simply wrong.

As can be seen in Figure 2A and 2B of Chang, above, the oval-shaped item 16, shown in the narrowed portion 17 near the base of the tip protector, is the gasket 16 through which the needle projects, as is described at column 5, lines 7 through 10, and lines 30 through 34 of Chang. The gasket 16 stays in that location (at the narrowed portion 17) irrespective of whether the needle is projecting through the tip protector with the needle tip extending therefrom (as in Figure 1) or is retracted with the needle tip enclosed within the tip protector (as in Figure 2C). Moreover, that the number was simply not included in Figure 2C is not an invitation to rewrite Chang as if the oval-shaped member had suddenly morphed into something other than a gasket. And, in addition to the foregoing, if the oval-shaped member were a crimp, then Examiner must point to some other portion of the device in the Chang patent as the gasket (another element required by the present claims). Examiner has not, and cannot, do so.

Other drawings in the case also make crystal clear that the oval-shaped member is affixed to the tip protector housing for the needle to move through, and so cannot be "fixedly coupled" to the needle shaft at a "predetermined location" thereof. For example, see Figs. 3A and 3B, reproduced below.

FIG. 3A

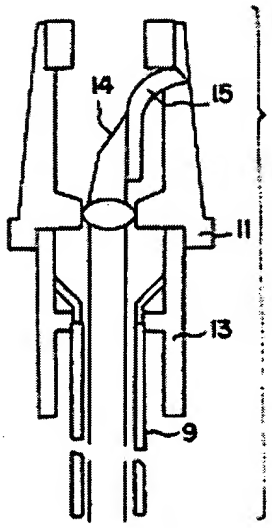


FIG. 3B

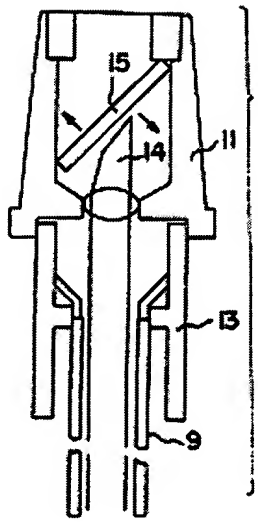


Fig. 3A shows a needle being retracted prior to deflection of the tab to block distal opening. Fig. 3B shows the same tip protector following deflection of the tab to block the distal opening. Regardless of position, oval-shaped member remains in narrowed portion of tip protector superstructure. Additionally, once tab has deflected (Fig. 3B), there is clearance between needle tip 14 and tab 15. Thus, the needle can be moved back and forth a slight distance within tip protector. As this occurs, the oval-shaped member would remain in the same position in the narrowed portion of superstructure and would not move with needle. Thus, it is clear that oval-shaped member (gasket) cannot be "fixedly coupled" to the needle shaft at "a predetermined distance" from the needle tip.

Thus, there is absolutely no basis in fact to consider that oval-shaped member to be a crimp on the needle. If it were such a crimp, it would move with the needle shaft. But the drawings in the case (including the very drawings cited by Examienr) make clear that the oval-

shaped member is affixed to the tip protector housing, and so does not move with the needle. Hence, it cannot be a crimp, or other irregularity, on the needle.

C. The Amendment to Recite "Fixedly Coupled" Does Not Add New Matter

As an ancillary matter, in the Office Action dated January 12, 2005, Examiner states that the "fixedly coupled" language (added by amendment in the RCE) is new matter because it is not disclosed anywhere in the specification. However, Examiner never specifically listed any claim as being rejected for new matter, nor is there a basis for such a rejection.

As can be seen from claim 1, "fixedly coupled" refers to the means on the needle shaft for impeding movement. As described above, this means is described in the application at page 6, lines 6-18 as (1) a crimp 70 created at a specific location of the needle shaft, or (2) a protuberance applied over a specific location the outer surface of the needle cannula shaft (such as by soldering or pressure fitting a durable O-ring therearound). Appellant submits that such "means" would clearly be fixedly coupled to the needle shaft. Any crimp that is a deformity of the needle cannula shaft simply must be integral with the shaft itself, and therefore must be fixedly coupled to the shaft. And, alternatively, the coupling of any protuberance by soldering or pressure fitting would result in a protuberance that moves with the needle shaft, and thus would necessarily be fixedly coupled thereto. Thus, that the words "fixedly coupled" do not appear in haec verba in the specification is immaterial as the disclosure clearly shows that relationship between the "means" and the needle shaft.

Conclusion

For the foregoing reasons, Appellant submits that Examiner's rejection is in error and a reversal of the rejection and allowance of the claims is therefore requested.

Enclosed is a check in the amount of $500.00 under 37 C.F.R. § 41.20(b)(2) for the fee for this submission. It is believed that no other fee is due. If, however, it is determined that any other fees are due, please charge same to Deposit Account No. 23-3000.

Respectfully submitted,

WOOD, HERRON & EVANS, L.L.P.

By: _____
David E. Jefferies
Reg. No. 46,800

Wood, Herron & Evans, L.L.P.
2700 Carew Tower
Cincinnati, Ohio 45202
(513) 241-2324 (telephone)
(513) 241-6234 (facsimile)

Claim Appendix

1. An apparatus comprising:

a needle cannula having a distal point, a proximal end and further having a shaft with a circumference;

a tip protector having a base, the tip protector defining an opening to receive the needle cannula shaft and the tip protector is slideably mounted thereon;

means coupled to the tip protector for blocking the tip protector opening so as to enclose the distal point of the needle cannula within the top protector;

a gasket coupled to the tip protector base defining an opening of a size to receive the needle cannula shaft;

means fixedly coupled to the needle cannula shaft at a predetermined location of the shaft for impeding movement of the tip protector along the needle cannula shaft beyond a pre-determined distance from the needle cannula distal point.

2. The apparatus of claim 1 further comprising a flash chamber coupled to the needle cannula at the need cannula proximal end.

3. The apparatus of claim 1, wherein the gasket is formed in place at the tip protector base of an adhesive material.

4. The apparatus of claim 3, wherein the gasket adhesive material is selected from the group consisting of paraffin, polyester and polyamide.

5. The apparatus of claim 3, wherein the gasket adhesive material is cured by exposure to ultraviolet light.

6. The apparatus of claim 1 wherein the blocking means comprises:

a tab having a length sufficient to block the tip protector opening, the tab pivotably coupled to the tip protector within the tip protector opening and slideably engaging the needle cannula shaft in a first biased position such that upon removal of the needle cannula shaft the tab is free to pivot to a second position extending across the tip protector opening.

7. The apparatus of claim 1 wherein the impeding means comprises:

an irregularity in the needle cannula shaft circumference a pre-determined distance from the needle cannula distal point occluding passing of the needle cannula shaft through the gasket opening.

8. The apparatus of claim 6, wherein the tab is an anti-stick metal tab.

9. The apparatus of claim 7, wherein the irregularity is a crimp inscribed in the needle cannula shaft.

10. The apparatus of claim 6, wherein the tip protector further comprises:

a superstructure coupled to the base;

a cylindrical anti-stick metal clip housed within the superstructure defining an opening to receive the needle cannula shaft, the clip housing the tab, the tab disposed within the clip opening such that in its first position the tab is biased against the needle cannula shaft and in its second position the tab pivots to block the clip opening.

11. The apparatus of claim 10, wherein the tip protector is optically transparent, the cylindrical clip opening is a first opening, and the clip further defines a second opening extending over a portion of the cylindrical circumference exposing a portion of the first opening.

Evidence Appendix

Exh. A. "Notice of Allowability" dated September 25, 2001

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

TMC

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

RECEIVED
OCT 01 2001
Johnson

QM52/0925

BLAKELY SOKOLOFF TAYLOR & ZAFMAN
7TH FLOOR
12400 WILSHIRE BOULEVARD
LOS ANGELES CA 90025

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN
LOS ANGELES

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/476,429	12/30/99	003	NGUYEN, A	3763 09/25/01

First Named Applicant	CHANG,	35 USC 154(b) term ext. =	0 Days.

TITLE OF INVENTION: SAFETY INTRAVENOUS CATHETER

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
3 056301.P482	604-164.080	M54	UTILITY	NO	$1240.00	12/26/01

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.
If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

A. Pay FEE DUE shown above, or

B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

ENTERED
OCT - 2 2001
STATUS DB-LA

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

YOUR COPY

Form PTO 948 (Rev. 8-98) U.S. DEPARTMENT OF COMMERCE - Patent and Trademark Office Application No. _____

NOTICE OF DRAFTSPERSON'S PATENT DRAWING REVIEW

The drawing(s) filed (insert date) 12/31/99 are:

A. ☐ approved by the Draftsperson under 37 CFR 1.84 or 1.152.

B. ☑ objected to by the Draftsperson under 37 CFR 1.84 or 1.152 for the reasons indicated below. The Examiner will require submission of new, corrected drawings when necessary. Corrected drawing must be sumitted according to the instructions on the back of this notice.

1. DRAWINGS. 37 CFR 1.84(a): Acceptable categories of drawings: Black ink. Color.
   - ____ Color drawings are not acceptable until petiton is granted. Fig(s) _____
   - ____ Pencil and non black ink not permitted. Fig(s) _____
2. PHOTOGRAPHS. 37 CFR 1.84 (b)
   - ____ 1 full-tone set is required. Fig(s) _____
   - ____ Photographs not properly mounted (must use brystol board or photographic double-weight paper). Fig(s) _____
   - ____ Poor quality (half-tone). Fig(s) _____
3. TYPE OF PAPER. 37 CFR 1.84(e)
   - ____ Paper not flexible, strong, white, and durable. Fig(s) _____
   - ____ Erasures, alterations, overwritings, interlineations, folds, copy machine marks not accepted. Fig(s) _____
   - ____ Mylar, velum paper is not acceptable (too thin). Fig(s) _____
4. SIZE OF PAPER. 37 CFR 1.84(f): Acceptable sizes:
   - ____ 21.0 cm by 29.7 cm (DIN size A4)
   - ____ 21.6 cm by 27.9 cm (8 1/2 x 11 inches)
   - ____ All drawing sheets not the same size. Sheet(s) _____
   - ____ Drawings sheets not an acceptable size. Fig(s) _____
5. MARGINS. 37 CFR 1.84(g): Acceptable margins:

   Top 2.5 cm Left 2.5cm Right 1.5 cm Bottom 1.0 cm
   SIZE: A4 Size

   Top 2.5 cm Left 2.5 cm Right 1.5 cm Bottom 1.0 cm
   SIZE: 8 1/2 x 11

   Margins not acceptable. Fig(s) _____

   _____ Top (T) _____ Left (L)

   _____ Right (R) _____ Bottom (B)
6. VIEWS. 37 CFR 1.84(h)

   REMINDER: Specification may require revision to correspond to drawing changes.

   Partial views. 37 CFR 1.84(h)(2)
   - ____ Brackets needed to show figure as one entity. Fig(s) _____
   - ____ Views not labeled separately or properly. Fig(s) _____
   - ____ Enlarged view not labeled separetely or properly. Fig(s) _____
7. SECTIONAL VIEWS. 37 CFR 1.84 (h)(3)
   - ____ Hatching not indicated for sectional portions of an object. Fig(s) _____
   - ____ Sectional designation should be noted with Arabic or Roman numbers. Fig(s) _____
8. ARRANGEMENT OF VIEWS. 37 CFR 1.84(i)
   - ____ Words do not appear on a horizontal, left-to-right fashion when page is either upright or turned so that the top becomes the right side, except for graphs. Fig(s) _____
9. SCALE. 37 CFR 1.84(k)
   - ____ Scale not large enough to show mechanism without crowding when drawing is reduced in size to two-thirds in reproduction. Fig(s) _____
10. CHARACTER OF LINES, NUMBERS, & LETTERS. 37 CFR 1.84(i)
   - ____ Lines, numbers & letters not uniformly thick and well defined, clean, durable, and black (poor line quality). Fig(s) _____
11. SHADING. 37 CFR 1.84(m)
   - ____ Solid black areas pale. Fig(s) _____
   - ____ Solid black shading not permitted. Fig(s) _____
   - ____ Shade lines, pale, rough and blurred. Fig(s) _____
12. NUMBERS, LETTERS, & REFERENCE CHARACTERS. 37 CFR 1.84(p)
   - ____ Numbers and reference characters not plain and legible. Fig(s) _____
   - ____ Figure legends are poor. Fig(s) _____
   - ____ Numbers and reference characters not oriented in the same direction as the view. 37 CFR 1.84(p)(1) Fig(s) _____
   - ____ English alphabet not used. 37 CFR 1.84(p)(2) Figs _____
   - ____ Numbers, letters and reference characters must be at least .32 cm (1/8 inch) in height. 37 CFR 1.84(p)(3) Fig(s) _____
13. LEAD LINES. 37 CFR 1.84(q)
   - ____ Lead lines cross each other. Fig(s) _____
   - ____ Lead lines missing. Fig(s) _____
14. NUMBERING OF SHEETS OF DRAWINGS. 37 CFR 1.84(t)
   - ____ Sheets not numbered consecutively, and in Arabic numerals beginning with number 1. Sheet(s) _____
15. NUMBERING OF VIEWS. 37 CFR 1.84(u)
   - ____ Views not numbered consecutively, and in Arabic numerals, beginning with number 1. Fig(s) _____
16. CORRECTIONS. 37 CFR 1.84(w)
   - ____ Corrections not made from prior PTO-948 dated _____
17. DESIGN DRAWINGS. 37 CFR 1.152
   - ____ Surface shading shown not appropriate. Fig(s) _____
   - ____ Solid black shading not used for color contrast. Fig(s) _____

COMMENTS

REVIEWER _____ DATE 9/24/01 TELEPHONE NO. _____

ATTACHMENT TO PAPER NO. 3

Notice of Allowability	Application No.	Applicant(s)	
	09/476,429	CHANG, JOSEPH J.	
	Examiner	Art Unit	
	Anh-Tuan T. Nguyen	3763	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address–

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the response to the Election of Species telephonically on 09/21/01*.
2. ☒ The allowed claim(s) is/are *12-14; now renumbered claims 1-3*.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All . b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
   (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

8. ☒ CORRECTED DRAWINGS must be submitted.
   (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☒ hereto or 2) ☐ to Paper No. _____.
   (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
   (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1☐ Notice of References Cited (PTO-892)
2☐ Notice of Informal Patent Application (PTO-152)
3☒ Notice of Draftperson's Patent Drawing Review (PTO-948)
4☐ Interview Summary (PTO-413), Paper No._____.
5☒ Information Disclosure Statements (PTO-1449), Paper No. 2.
6☒ Examiner's Amendment/Comment
7☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
8☒ Examiner's Statement of Reasons for Allowance
9☐ Other

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species I: Figure 1 (claims 1-11); and

Species II: Figure 2 (claims 12-14).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Mr. Thomas Coester on 09/21/01 a provisional election was made without traverse to prosecute the invention of Species II, claims 12-14. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-11 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

EXAMINER'S AMENDMENT

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

Claims 1-11 have been canceled. These claims have been canceled by the examiner as being directed toward a non-elected species without traverse. The applicant has reserved the rights to re-file these claims in a divisional application.

REASONS FOR ALLOWANCE

4. The following is an examiner's statement of reasons for allowance:

The claimed invention is found to be allowable because the prior art searched and those of record do not disclose or fairly suggest a motivation to combine a medical intravenous catheter comprising, inter alia, a flash chamber further having walls extending from the flash chamber distal end defining a space to receive the tip protector; an anti-stick metal clip housed

within the tip protector; a biased tab of a length sufficient to extend across the clip opening pivotably disposed within the clip opening such that, in its first position, the tab engages the needle cannula shaft and when the shaft is withdrawn, the tab pivots to occupy a second position blocking the clip opening; a formed in place gasket at the base of the tip protector; a crimp inscribed into the needle cannula shaft, wherein moving the tip protector to the point where the crimp occludes the needle cannula shaft, through the gasket opening, thus moves the tab beyond the needle cannula shaft so as to free the tab to pivot to its second position; and a flash plug.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anh-Tuan T. Nguyen whose telephone number is 703-308-2154. The examiner can normally be reached on Mon-Fri, 0830-1800 hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Richard Seidel, can be reached on 703-308-5115. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Anh-Tuan T. Nguyen
Primary Examiner
Art Unit 3763

ATN
September 24, 2001